ASSEMBLY BILL No. 378

Introduced by Assembly Member Solorio

February 14, 2011

An act to amend Sections 139.3 and 139.31 of the Labor Code, relating to workers' compensation.

LEGISLATIVE COUNSEL'S DIGEST

AB 378, as introduced, Solorio. Workers' compensation: pharmacy products.

Existing law establishes a workers' compensation system, administered by the Administrative Director of the Division of Workers' Compensation, to compensate an employee for injuries sustained in the course of employment.

Existing law provides that it is unlawful for a physician to refer a person for specified medical goods or services whether for treatment or medical-legal purposes if the physician or his or her immediate family has a financial interest with the person or in the entity that receives the referral, except in prescribed circumstances. A violation of this provision is a misdemeanor.

This bill would add pharmacy goods, as defined, to the list of medical goods or services for which it is unlawful for a physician to refer a person under this provision, except in prescribed circumstances. By creating a new crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) In 2002, the Legislature passed Assembly Bill 749 (Chapter 6 of the Statutes of 2002), which directed an official medical fee schedule for pharmaceuticals to be created to contain workers' compensation costs and to ensure that injured workers had access to appropriate treatment.

(b) Since the creation of the official medical fee schedule governing pharmaceuticals, there has been a growing practice by some prescribing physicians to utilize medications that are not covered by the fee schedule, to dispense these medications directly to workers' compensation patients, and to bill employers and insurers at highly inflated rates. These practices unfairly enrich the physicians who engage in these efforts, cost employers and insurers millions of dollars, and prevent these wasted dollars from being used to enhance benefits for injured workers.

(c) One of the ways that these physicians accomplished the goal of billing at inflated rates was by repackaging common medications from bulk supplies so that the packages did not have fee schedule codes, and dispensing them in common amounts at prices far above the fee schedule for the same products sold through pharmacies. This practice continued until the Administrative Director of the Division of Workers' Compensation adopted a regulation in 2007 that required any repackaged medication to be reimbursed at the same fee schedule as the same drug distributed through pharmacies and not reimbursed based on arbitrary prices associated with unscheduled packages.

(d) Prior to the adoption of the physician dispensing regulation, compounded medications, creams, copacks, and other medical foods constituted a small percentage of the overall cost of prescription medications. However, once the abusive repackaging practice was outlawed, the practice of physicians prescribing or

dispensing compounded medications, creams, copacks, and medical foods expanded rapidly.

(e) The percentage of California workers' compensation medication dollars that are used toward compound drugs, copacks, and medical foods has increased from 2.3 percent in 2006 to 12 percent in 2009. This increase in compound drugs, copacks, and medical foods has increased costs for insurers and led to rising premiums for employers. For example, the State Compensation Insurance Fund reports that what was rarely billed prior to 2007 rapidly escalated to over $58 million in billings in a 16-month period. Another insurer reported a 16-fold increase in less than a two year period.

(f) Compounded drugs are not evaluated for safety or efficacy by the federal Food and Drug Administration (FDA). According to the FDA, compound drugs carry significant health risks that can lead to permanent injury or death.

(g) In order to alleviate California's employers and insurers from this significant increase in costs, to enhance the efficiency of the workers' compensation system, and to ensure that injured workers receive safe, appropriate health care, the Legislature hereby declares the need to remove the financial incentive for prescribing costly and questionable compounded drugs, copacks, and medical foods and to create a new process for the prescription of compound drugs, copacks, and medical foods.

SEC. 2. Section 139.3 of the Labor Code is amended to read:

139.3. (a) Notwithstanding any other ~~provision of~~ law, to the extent those services are paid pursuant to Division 4 (commencing with Section 3200), it is unlawful for a physician to refer a person for clinical laboratory, diagnostic nuclear medicine, radiation oncology, physical therapy, physical rehabilitation, psychometric testing, home infusion therapy, outpatient surgery, ~~or~~ diagnostic imaging goods or services, *or pharmacy goods,* whether for treatment or medical-legal purposes, if the physician or his or her immediate family~~,~~ has a financial interest with the person or in the entity that receives the referral.

(b) For purposes of this section and Section 139.31, the following shall apply:

(1) "Diagnostic imaging" includes, but is not limited to, all X-ray, computed axial tomography magnetic resonance imaging,

nuclear medicine, positron emission tomography, mammography, and ultrasound goods and services.

(2) "Immediate family" includes the spouse and children of the physician, the parents of the physician, and the spouses of the children of the physician.

(3) "Physician" means a physician as defined in Section 3209.3.

(4) A "financial interest" includes, but is not limited to, any type of ownership, interest, debt, loan, lease, compensation, remuneration, discount, rebate, refund, dividend, distribution, subsidy, or other form of direct or indirect payment, whether in money or otherwise, between a licensee and a person or entity to whom the physician refers a person for a good or service specified in subdivision (a). A financial interest also exists if there is an indirect relationship between a physician and the referral recipient, including, but not limited to, an arrangement whereby a physician has an ownership interest in any entity that leases property to the referral recipient. Any financial interest transferred by a physician to, or otherwise established in, any person or entity for the purpose of avoiding the prohibition of this section shall be deemed a financial interest of the physician.

(5) A "physician's office" is either of the following:

(A) An office of a physician in solo practice.

(B) An office in which the services or goods are personally provided by the physician or by employees in that office, or personally by independent contractors in that office, in accordance with other provisions of law. Employees and independent contractors shall be licensed or certified when that licensure or certification is required by law.

(6) The "office of a group practice" is an office or offices in which two or more physicians are legally organized as a partnership, professional corporation, or not-for-profit corporation licensed according to subdivision (a) of Section 1204 of the Health and Safety Code for which all of the following are applicable:

(A) Each physician who is a member of the group provides substantially the full range of services that the physician routinely provides, including medical care, consultation, diagnosis, or treatment, through the joint use of shared office space, facilities, equipment, and personnel.

(B) Substantially all of the services of the physicians who are members of the group are provided through the group and are

billed in the name of the group and amounts so received are treated as receipts of the group, and except that in the case of multispecialty clinics, as defined in subdivision (*l*) of Section 1206 of the Health and Safety Code, physician services are billed in the name of the multispecialty clinic and amounts so received are treated as receipts of the multispecialty clinic.

(C) The overhead expenses of, and the income from, the practice are distributed in accordance with methods previously determined by members of the group.

(7) Outpatient surgery includes both of the following:

(A) Any procedure performed on an outpatient basis in the operating rooms, ambulatory surgery rooms, endoscopy units, cardiac catheterization laboratories, or other sections of a freestanding ambulatory surgery clinic, whether or not licensed under paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code.

(B) The ambulatory surgery itself.

(8) "Pharmacy goods" means any dangerous drug or dangerous device as defined by Section 4022 of the Business and Professions Code, and any medical food as defined by Section 109971 of the Health and Safety Code.

(c) (1) It is unlawful for a licensee to enter into an arrangement or scheme, such as a cross-referral arrangement, that the licensee knows, or should know, has a principal purpose of ensuring referrals by the licensee to a particular entity that, if the licensee directly made referrals to that entity, would be in violation of this section.

(2) It shall be unlawful for a physician to offer, deliver, receive, or accept any rebate, refund, commission, preference, patronage dividend, discount, or other consideration, whether in the form of money or otherwise, as compensation or inducement for a referred evaluation or consultation.

(d) No claim for payment shall be presented by an entity to any individual, third-party payor, or other entity for any goods or services furnished pursuant to a referral prohibited under this section.

(e) A physician who refers to or seeks consultation from an organization in which the physician has a financial interest shall disclose this interest to the patient or if the patient is a minor, to

the patient's parents or legal guardian in writing at the time of the referral.

(f) No insurer, self-insurer, or other payor shall pay a charge or lien for any goods or services resulting from a referral in violation of this section.

(g) A violation of subdivision (a) shall be a misdemeanor. The appropriate licensing board shall review the facts and circumstances of any conviction pursuant to subdivision (a) and take appropriate disciplinary action if the licensee has committed unprofessional conduct. Violations of this section may also be subject to civil penalties of up to five thousand dollars ($5,000) for each offense, which may be enforced by the Insurance Commissioner, Attorney General, or a district attorney. A violation of subdivision (c), (d), (e), or (f) is a public offense and is punishable upon conviction by a fine not exceeding fifteen thousand dollars ($15,000) for each violation and appropriate disciplinary action, including revocation of professional licensure, by the Medical Board of California or other appropriate governmental agency.

SEC. 3. Section 139.31 of the Labor Code is amended to read:

139.31. The prohibition of Section 139.3 shall not apply to or restrict any of the following:

(a) A physician may refer a patient for a good or service otherwise prohibited by subdivision (a) of Section 139.3 if the physician's regular practice is where there is no alternative provider of the service within either 25 miles or 40 minutes traveling time, via the shortest route on a paved road. A physician who refers to, or seeks consultation from, an organization in which the physician has a financial interest under this subdivision shall disclose this interest to the patient or the patient's parents or legal guardian in writing at the time of referral.

(b) A physician who has one or more of the following arrangements with another physician, a person, or an entity, is not prohibited from referring a patient to the physician, person, or entity because of the arrangement:

(1) A loan between a physician and the recipient of the referral, if the loan has commercially reasonable terms, bears interest at the prime rate or a higher rate that does not constitute usury, is adequately secured, and the loan terms are not affected by either party's referral of any person or the volume of services provided by either party.

(2) A lease of space or equipment between a physician and the recipient of the referral, if the lease is written, has commercially reasonable terms, has a fixed periodic rent payment, has a term of one year or more, and the lease payments are not affected by either party's referral of any person or the volume of services provided by either party.

(3) A physician's ownership of corporate investment securities, including shares, bonds, or other debt instruments that were purchased on terms that are available to the general public through a licensed securities exchange or NASDAQ, do not base profit distributions or other transfers of value on the physician's referral of persons to the corporation, do not have a separate class or accounting for any persons or for any physicians who may refer persons to the corporation, and are in a corporation that had, at the end of the corporation's most recent fiscal year, total gross assets exceeding one hundred million dollars ($100,000,000).

(4) A personal services arrangement between a physician or an immediate family member of the physician and the recipient of the referral if the arrangement meets all of the following requirements:

(A) It is set out in writing and is signed by the parties.

(B) It specifies all of the services to be provided by the physician or an immediate family member of the physician.

(C) The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement.

(D) A written notice disclosing the existence of the personal services arrangement and including information on where a person may go to file a complaint against the licensee or the immediate family member of the licensee, is provided to the following persons at the time any services pursuant to the arrangement are first provided:

(i) An injured worker who is referred by a licensee or an immediate family member of the licensee.

(ii) The injured worker's employer, if self-insured.

(iii) The injured worker's employer's insurer, if insured.

(iv) If the injured worker is known by the licensee or the recipient of the referral to be represented, the injured worker's attorney.

(E) The term of the arrangement is for at least one year.

(F) The compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties, except that if the services provided pursuant to the arrangement include medical services provided under Division 4, compensation paid for the services shall be subject to the official medical fee schedule promulgated pursuant to Section 5307.1 or subject to any contract authorized by Section 5307.11.

(G) The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law.

(c) (1) A physician may refer a person to a health facility as defined in Section 1250 of the Health and Safety Code, to any facility owned or leased by a health facility, or to an outpatient surgical center, if the recipient of the referral does not compensate the physician for the patient referral, and any equipment lease arrangement between the physician and the referral recipient complies with the requirements of paragraph (2) of subdivision (b).

(2) Nothing shall preclude this subdivision from applying to a physician solely because the physician has an ownership or leasehold interest in an entire health facility or an entity that owns or leases an entire health facility.

(3) A physician may refer a person to a health facility for any service classified as an emergency under subdivision (a) or (b) of Section 1317.1 of the Health and Safety Code. For nonemergency outpatient diagnostic imaging services performed with equipment for which, when new, has a commercial retail price of four hundred thousand dollars ($400,000) or more, the referring physician shall obtain a service preauthorization from the insurer, or self-insured employer. Any oral authorization shall be memorialized in writing within five business days.

(d) A physician compensated or employed by a university may refer a person to any facility owned or operated by the university, or for a physician service, to another physician employed by the university, provided that the facility or university does not compensate the referring physician for the patient referral. For nonemergency diagnostic imaging services performed with equipment that, when new, has a commercial retail price of four

hundred thousand dollars ($400,000) or more, the referring physician shall obtain a service preauthorization from the insurer or self-insured employer. An oral authorization shall be memorialized in writing within five business days. In the case of a facility which is totally or partially owned by an entity other than the university, but which is staffed by university physicians, those physicians may not refer patients to the facility if the facility compensates the referring physician for those referrals.

(e) The prohibition of Section 139.3 shall not apply to any service for a specific patient that is performed within, or goods that are supplied ~~by~~ *for use within*, a physician's office, or the office of a group practice. Further, the provisions of Section 139.3 shall not alter, limit, or expand a physician's ability to deliver, or to direct or supervise the delivery of, in-office goods or services according to the laws, rules, and regulations governing his or her scope of practice. With respect to diagnostic imaging services performed with equipment that, when new, had a commercial retail price of four hundred thousand dollars ($400,000) or more, ~~or~~ for physical therapy services, *for pharmacy goods furnished for use outside the physician's office for which the referring physician's office or group practice charges more than the documented paid cost net of any rebates or refunds or discounts plus the lesser of 20 percent of the documented paid cost or one hundred dollars ($100),* or for psychometric testing that exceeds the routine screening battery protocols, with a time limit of two to five hours, established by the administrative director, the referring physician ~~obtains~~ *shall obtain* a service preauthorization from the insurer or self-insured employer. Any oral authorization shall be memorialized in writing within five business days.

(f) The prohibition of Section 139.3 shall not apply where the physician is in a group practice as defined in Section 139.3 and refers a person for services specified in Section 139.3 to a multispecialty clinic, as defined in subdivision (*l*) of Section 1206 of the Health and Safety Code. For diagnostic imaging services performed with equipment that, when new, had a commercial retail price of four hundred thousand dollars ($400,000) or more, ~~or~~ physical therapy services, ~~or~~ *for pharmacy goods furnished for use outside the physician's office for which the referring physician's office or group practice charges more than the documented paid cost net of any rebates or refunds or discounts*

plus the lesser of 20 percent of the documented paid cost or one hundred dollars ($100), psychometric testing that exceeds the routine screening battery protocols, with a time limit of two to five hours, established by the administrative director, performed at the multispecialty facility, the referring physician shall obtain a service preauthorization from the insurer or self-insured employer. Any oral authorization shall be memorialized in writing within five business days.

(g) The requirement for preauthorization in Sections (c), (e), and (f) shall not apply to a patient for whom the physician or group accepts payment on a capitated risk basis.

(h) The prohibition of Section 139.3 shall not apply to any facility when used to provide health care services to an enrollee of a health care service plan licensed pursuant to the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).

(i) The prohibition of Section 139.3 shall not apply to an outpatient surgical center, as defined in paragraph (7) of subdivision (b) of Section 139.3, where the referring physician obtains a service preauthorization from the insurer or self-insured employer after disclosure of the financial relationship.

SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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